



JAN 22 2001

510(k) SUMMARY

K 003688

1 DATE PREPARED

November 24, 2000.

2 CONTACT PERSON

Jean-Luc Des Groseilliers
Executive Vice-President

3 DEVICE NAME

Proprietary Name:	VIEW READING STATION™
Common Name:	DICOM Reading Station;
Radiology Panel	90LLZ - System, Image Processing
Classification Name:	Picture Archiving and Communications Systems (PACS)
	21CFR892.2050
	(Federal Register / Vol. 63, No. 82 / April 29, 1998)

4 DEVICE DESCRIPTION AND INTENDED USE

The VIEW Reading Station™ is a DICOM Reading Station which allows the visualization of studies encapsulated in DICOM format stored locally, in other servers (connected through the same network) or in CD-ROM. The VIEW Reading Station™ is physically linked to a TCP/IP type network

The VIEW Reading Station™ allows the real time visualization of cine and/or still images encapsulated in DICOM format, as well as cine and/or still images contained in a CD-DICOM. It can also allow certain image enhancement functions such as Zoom, Pan, Contrast Brightness, Filters and multi-frame image speed playback control

5 SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE(S)

Substantially Equivalent (Predicate) Devices

Product Tradename	Manufacturer	510(k) Number
VIEW NT	Electromed International	K000474
View Archiving Station (VAS)	Electromed International	K971176
Video Plus with Analytical Workstation	Camtronics	K941979
Cine Net	Sony	K924708

6 SAFETY AND EFFECTIVENESS

The intended use and technological characteristic of the VIEW Reading Station™ are similar or equivalent to the Predicate Device(s). Any differences between the VIEW Reading Station™ and the Predicate Device(s) have no significant influence on the safety and/or effectiveness of the Device.

7 CLINICAL PERFORMANCE DATA

Not required for determination of substantial equivalence for this type and class of device.

8 CONCLUSION DRAWN FROM CLINICAL AND NONCLINICAL TEST DATA

Not required for determination of substantial equivalence for this type and class of device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2001

Jean-Luc Des Groseilliers
Executive Vice President
Electromed International Ltd.
310 Industrial Blvd.
St-Eustache, Quebec
CANADA

Re: K003688
View Reading Station™ (Model VRS5000™,
VRS2000™, VRS1000™ and PC View)
Dated: November 24, 2000
Received: November 30, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Des Groseilliers:

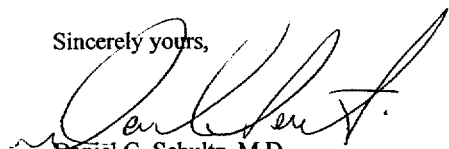
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)



Indication for Use Statement

510(k) Number:(if known):

K003688

Device Name:

VIEW Reading Station™

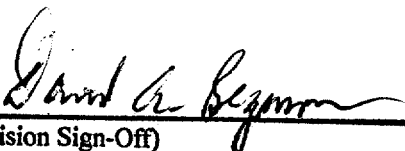
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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003688

Prescription Use

✓

OR

Over-the-Counter Use

(per 21CFR801.109)